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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,365	05/17/2002	John D. Steeves	MBM1260	1464

7590 12/31/2003

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EXAMINER	
NICHOLS, CHRISTOPHER J	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 12/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,365	STEEVES ET AL.	
	Examiner	Art Unit	
	Christopher Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 17 May 2002.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-59 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-59 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

2. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

3. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) **1-20, 37-43,** and **57-59 (each in part)**, drawn to a composition comprising *antibodies* and one or more *chimeric proteins* and method of manufacture thereof, classified in class 530, subclass 387.1, for example.

Group 2, claim(s) **1-21, 37-39,** and **57-59 (each in part)**, drawn to a composition comprising *antibodies* and one or more *polynucleotides* encoding said one or more chimeric proteins, classified in class 536, subclass 23.1, for example.

Group 3, claim(s) **1-20, 22-39,** and **57-59 (each in part)**, drawn to a composition comprising *antibodies* and *cells*, classified in class 435, subclass 325, for example.

Group 4, claim(s) **44-49** and **52-55 (each in part),** drawn to treatment of neuron dysfunction caused by injury or trauma to the CNS using a composition comprising *antibodies and chimeric proteins*, classified in class 424, subclass 130.1, for example.

Group 5, claim(s) **44-47** and **50-55 (each in part),** drawn to treatment of neuron dysfunction caused by disease using a composition comprising *antibodies and chimeric proteins*, classified in class 424, subclass 130.1, for example.

Group 6, claim(s) **44-49** and **52-55 (each in part),** drawn to treatment of neuron dysfunction caused by injury or trauma to the CNS using a composition comprising *antibodies and polynucleotides*, classified in class 514, subclass 44, for example.

Group 7, claim(s) **44-47** and **50-55 (each in part),** drawn to treatment of neuron dysfunction caused by disease using a composition comprising *antibodies and polynucleotides*, classified in class 514, subclass 44, for example.

Group 8, claim(s) **44-49** and **52-55 (each in part),** drawn to treatment of neuron dysfunction caused by injury or trauma to the CNS using a composition comprising *antibodies and cells*, classified in class 424, subclass 93.1, for example.

Group 9, claim(s) **44-47** and **50-55 (each in part),** drawn to treatment of neuron dysfunction caused by disease using a composition comprising *antibodies and cells*, classified in class 424, subclass 93.1, for example.

Group 10, claim(s) **56 (in part),** drawn to a method of detecting and monitoring the efficacy of a composition to cause focal transient disruption and/or transited demyelination of mammalian neurons using a composition comprising *antibodies and chimeric proteins*, classified in class 424, subclass 130.1, for example.

Group 11, claim(s) **56 (in part),** drawn to a method of detecting and monitoring the efficacy of a composition to cause focal transient disruption and/or transited demyelination of mammalian neurons using a composition comprising *antibodies and polynucleotides*, classified in class 514, subclass 44, for example.

Group 12, claim(s) **56 (in part),** drawn to a method of detecting and monitoring the efficacy of a composition to cause focal transient disruption and/or transited demyelination of mammalian neurons using a composition comprising *antibodies and cells*, classified in class 424, subclass 93.1, for example.

4. The inventions listed as Groups 1-12 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group 1 recites the technical feature of a composition comprising *chimeric proteins*, which is not required by the other Groups 2-12.

Group 2 recites the technical feature of a composition comprising *polynucleotides*, which is not required by the other Groups 1 or 3-12.

Group 3 recites the technical feature of a composition comprising *cells*, which is not required by the other Groups 1, 2, or 4-12.

Group 4 recites the technical feature of treating injury using a composition comprising *chimeric proteins*, which is not required by the other Groups 1-3 or 4-12.

Group 5 recites the technical feature of treating disease using a composition comprising *chimeric proteins*, which is not required by the other Groups 1-4 or 6-12.

Group 6 recites the technical feature of treating injury using a composition comprising *polynucleotides*, which is not required by the other Groups 1-5 or 7-12.

Group 7 recites the technical feature of treating disease using a composition comprising *polynucleotides*, which is not required by the other Groups 1-6 or 8-12.

Group 8 recites the technical feature of treating injury using a composition comprising *cells*, which is not required by the other Groups 1-7 or 9-12.

Group 9 recites the technical feature of treating disease using a composition comprising *cells*, which is not required by the other Groups 1-8 or 10-12.

Group 10 recites the technical feature of detecting and monitoring the efficacy of a composition comprising *chimeric proteins*, which is not required by the other Groups 1-9 or 11-12.

Group 11 recites the technical feature of detecting and monitoring the efficacy of a composition comprising *polynucleotides*, which is not required by the other Groups 1-10 or 12.

Group 12 recites the technical feature of detecting and monitoring the efficacy of a composition comprising *cells*, which is not required by the other Groups 1-11.

5. This application contains claims directed to the following patentably distinct species of the claimed invention:

a. Galactocerebroside (GalC)

b. O4

c. Myelin Associated Glycoprotein (MAG)

d. NOGO

e. NI220

f. NI-35/250

g. Myelin oligodendrocyte glycoprotein (MOG)

h. Arretin

6. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, **1** is generic.

7. If applicant selects any one of Groups 1-12, one species from the epitope of a mammalian myelin group must be chosen to be fully responsive.

8. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

11. The Examiner has required restriction between product and method claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn method claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Method claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

12. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined method claims will be withdrawn, and the rejoined method claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and method claims may be maintained. Withdrawn method claims that are not commensurate in scope with an allowed product claim will not be rejoined.

See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the method claims should be amended during prosecution either to maintain dependency on the method claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

13. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

14. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

15. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:00AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN
December 15, 2003

Gary A. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600